

In particular, the Examiner states that the inventions listed in Groups I – III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. In this case, the Examiner states that the film-shaped administration form described in claim 1 of the present application is known in the prior art. The Examiner further states that EP0386960 (Gibson, et al.) discloses pharmaceutical compositions for the delivery of active compounds with reversible thermosetting gel properties and film-forming properties (Abstract). The Examiner still further states that polyvinyl alcohol, hydroxypropylmethylcellulose or hydroxyethylcellulose can be used as the film former (page 5, lines 4-5) and the pH of the composition can be between 3 to 9 (page 9, lines 34-44).

The Applicants hereby elect the claims of Group I (which reads on claims 1-15 and 20-29) for further prosecution on the merits thereof. In view of the above election, the Applicants respectfully object to the instant restriction requirement, with traverse, as discussed below.

It is respectfully submitted that the present restriction requirement is not justifiable in this instance since independent claim 16 of Group II relates to a manufacturing process for producing the administration forms claimed in the claims of Group I, and claim 15 of Group III relates to the medical/therapeutical use of the products claimed in the claims of Group I. Therefore, it is submitted that the present claims are interrelated with each other due to the fact that they refer to the same kind of product.

The Applicants further submit that Gibson, et al. fail to disclose directly and

unequivocally the film-shaped administration forms for transmucosal administration as presently claimed. The drug delivery compositions taught by Gibson, et al. comprise an aqueous vehicle and they are formulated as a pourable liquid or gel (page 2, lines 41-42, line 50 – page 3, line 2). In contrast, present claims 1 and 16 pertain to dried film.


Although Gibson, et al. teach the pH of the composition, this passage does not relate to film-shaped administration forms for transmucosal administration and it does not relate to dried films (as set forth in present claims 1 and 16).

In view of the above, the Applicants respectfully submit that the Examiner's position that the film-shaped administration form described in present claim 1 was known in the prior art is incorrect. In turn, the Applicants submit that since the subject matter of present claims 1 and 16 are not anticipated by Gibson, et al., the claims of the present application are in fact linked by a common technical feature and relate to a single general inventive concept. Therefore, withdrawal of this restriction requirement and further prosecution of all the present claims is respectfully requested.

The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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